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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,438

07/13/2004

Andras Bertha

BERTHA-4

9435

21710

7590

10/25/2006

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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,438

Applicant(s)

BERTHA, ANDRAS

Examiner

Rosanne Kosson

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1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on September 25, 2006 has been received and entered. Claim 4 has been amended. Claims 3 and 5-24 have been canceled. Claims 25-26 have been added. Claims 1-2 were previously withdrawn as being drawn to a non-elected invention. Accordingly, claims 4, 25 and 26 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 26 is objected to because of the following informality. The active voice must be used when reciting method steps. Claim 26 may be amended to recite that the method further comprises an additional step, instead of reciting a wherein clause. Specifically, claim 26 may be amended to recite: "The method of claim 25, further comprising combining the upper layer and the diluted crust layer." Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

In view of Applicant's amendments to the claims, the enablement rejection is withdrawn. Upon reconsideration of the amended claims, however, the following rejection applies.

Claims 4, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the claims recite a method for obtaining an anti-tumor substance from colostrum,

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but one of skill in the art would not be able to practice the invention (i.e., use the invention) based on the disclosure in the claims. Thus, one of skill in the art would not be able to isolate an anti-tumor substance from colostrum.

The factors to be considered in determining whether or not undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome

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classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The *Wands* factors that pertinent in this case are 3) and 5) – 7).

3. The state of prior art.

The prior art does not disclose or suggest the claimed method. Thus, the prior art does not enable the claimed method. As previously discussed, Janusz et al. (US 2005/0152985) disclose that mammalian colostrum contains the polypeptide colostrinin, which has a number of biological activities, including stimulating the release of cytokines from lymphocytes (see paragraphs 1-3, 6, 7 and 44). Cytokines have anti-cancer properties and are administered to cancer patients (see *Cancer Principles & Practice of Oncology*, 6th Ed., De Vita et al., eds., Lippincott Williams & Wilkins, Philadelphia, 2001, pp. 308-312). Thus, it was known at the time of Applicant's invention that colostrum has anti-cancer properties. One of ordinary skill in the art would have expected these anti-cancer properties in colostrum from normal mammals and from animals with leucosis. But, colostrinin is not isolated by Applicant's method.

5. The level of predictability in the art.

Because it is not known that an anti-tumor agent can be isolated from colostrum by the claimed method, the specification needs to have more detail as how to make and use the

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invention. Because the necessary method steps are not completely described in the claims, it cannot be predicted that an anti-tumor substance may be isolated by practicing the method as claimed.

6. The amount of guidance present.

Applicants have not provided sufficient guidance for practicing the claimed method, because it is unclear what "the rest" in claim 4, step d) is. It is also unclear why steps d) – f) are performed and what is isolated by performing these steps. If the upper layer and the middle layer (the crust) are saved for later use, it is unclear why the rest is extracted with chloroform a second time. It is unclear where the anti-tumor substance is in all the fractions produced by the claimed method. Because of the lack of guidance, one of skill in the art would have to determine independently what "the rest" is, why steps d) – f) are necessary and which of the fractions produced by the claimed method contain an anti-tumor substance.

7. The existence of working examples.

The method steps discussed above appear to be a working example.

Therefore, the claims fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicant's amendments to the claims, the rejection in the previous Office action is withdrawn. Upon reconsideration of the amended claims, however, the following rejections apply.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is confusing because step c) recites that an upper layer and a medial layer (a crust) are separated from the rest. Presumably, these two layers are separated from each

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other, because they appear to be treated separately in claim 4, step g) and in claim 25, but the claim language of step c) is ambiguous. These two layers are separated from "the rest," which is treated in steps d) – f), but nothing is done with the product obtained in step f). Thus, it is not clear why steps d) – f) are performed or what product is obtained. It is also not clear what "the rest" is, i.e., whether it is an organic layer or an aqueous layer and whether or not it contains the anti-tumor substance. Clarification and correction are required, so that one of ordinary skill in the art would be able to reproduce the claimed method, in order to practice the invention.

Also, claim 25 recites the limitation "the medial jelly-like crust layer." There is insufficient antecedent basis for this limitation in the claim. To provide antecedent basis for all claim limitations, claim 4, part c) may be amended to recite the steps of separating the upper layer and separating the medial jelly-like crust layer. Appropriate correction is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

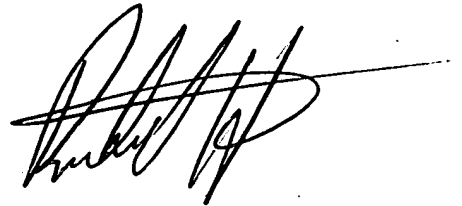
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2006-10-17

A handwritten signature in black ink, appearing to read 'David Hutson', with a long horizontal line extending from the end of the signature.

DAVID HUTSON, PH.D.
PRIMARY EXAMINER